AREA PRESCRIBING COMMITTEE – Birmingham, Sandwell, Solihull and environs

Decision Making Support Tool

The following document supports the committee to consider formulary applications against defined criteria.

Formulary application reference:	APCBSSE/0011
Drug name and formulations:	Indacaterol (Onbrez Breezhaler®)

Criteria	***Example***	**Committee Consensus**
Patient Safety	*Potential for abuse, toxicity, significant drug interactions*	Appears to have similar safety profile to salmeterol and formoterol, which are well established treatments. LABAs should be used with caution in patients with CV disease or rhythm disorders, and in patients with diabetes.
Clinical effectiveness	*Established licensed product*	Established licensed product. Indacaterol 150mcg once daily has demonstrated statistically significant improvements in lung function compared with salmeterol 50mcg twice daily in patients with moderate to severe COPD. The clinical significance of the observed differences in lung function is unclear, but short term data suggest significantly more patients using indacaterol 150mcg once daily achieved clinically relevant improvements in breathlessness and health status.
Strength of evidence		Robust evidence of sustained benefits over formoterol to warrant its higher acquisition cost is lacking. There is no evidence of benefits of indacaterol over tiotropium.
Cost effectiveness or resource impact	*£*	£355 pa. The acquisition costs of indacaterol are similar to the lower cost salmeterol products, which are over £200 greater per year than the lowest cost formoterol product.
Place of therapy relative to available treatments	*1/2nd tier*	Other more established LABAs on formulary.
National guidance and priorities	*NICE, MTRAC*	NICE guideline on management of COPD (2010). SMC accepted August 2010.
Local health priorities	*CCG views*	Cost-effective treatment of COPD is a priority in Primary Care.

Equity of access	*Equality assessment*	No restrictions.
Stakeholder views	*Define wider groups to be engaged*	Respiratory Network views considered (HEFT/City & Sandwell/ UHB)
Implementation requirements	*Requires, RICAD ESCA etc.*	Draft COPD guideline available.

Decision Summary

Resubmission is recommended to complete the information to enable a decision:	
Not approved and rationale:	This has been previously rejected by pre APC formulary committees. Robust evidence of sustained benefits over formoterol to warrant its higher acquisition cost is lacking. There is no evidence of benefits of indacaterol over tiotropium. On questioning, the clinicians strongly favoured the availability of glycopyrronium monocomponent inhaler, which is in the same device as indacaterol, but accepted that only 1 in 20 patients would start on a LABA instead of a LAMA due to patient factors (CV risk profile, unable to tolerate antimuscarinic side effects). The committee felt that 5% of patients who could not have a LAMA would be well served by existing formulary choices, so the case for another LABA was not made.
Formulary status (RAG) and rationale	
Implementation requirements:	
Implementation monitoring:	